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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/780,205	02/09/2001	Stanislaus Laurens Johan Wouters	4753US	7934

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TRASK BRITT
P.O. BOX 2550
SALT LAKE CITY, UT 84110

EXAMINER
BELYAVSKYI, MICHAIL A

ART UNIT	PAPER NUMBER
2644	9

DATE MAILED: 03/22/2002

Please find below and or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/780,205	WOUTERS ET AL
	Examiner	Art Unit
	Michail A Belyavskyi	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [·] Responsive to communication(s) filed on *09 February 2001*.

2a) [ ] This action is **FINAL**. 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) [·] Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) [ ] Claim(s) _____ is/are allowed.

6) [ ] Claim(s) _____ is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [X] Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are: a) [ ] accepted or b) [ ] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) [·] Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) [ ] All b) [ ] Some * c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____.
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) [ ] The translation of the foreign language provisional application has been received.

15) [ ] Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) [ ] Notice of References Cited (PTO-892)
2) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) [ ] Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) [ ] Interview Summary (PTO-413) Paper No(s). _____
5) [ ] Notice of Informal Patent Application (PTO-152)
6) [X] Other: *Restriction/election fax*

DETAILED ACTION

1. Applicant's amendments, filed 2 09 01 (Paper No 8), are acknowledged.
Claims 3, 9 13,14, 20, 27, 28, 30-32 have been amended.
Claims 1 – 32 *are pending.*

Restriction Requirement

2. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell *a* uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3. The following is noted:
Claims 2 is not a proper dependent claim of Claim 1, because it is drawn to a product not encompass by the scope of claim 1. Antibody and antibody-conjugated to active substance molecules differ with respect to their structure, a person of ordinary skill in the art would not envision one in view of the other. In addition, they differ in mode of action. Therefore, the restriction has been set forth for each as separate groups, irrespective of the format of the claims.

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1, 3-7, 9-12, 13-19, 30, 31, drawn to antibody, fragment thereof and composition, classified in Class 530, subclass 387.1, Class 424, subclass.130.1.

II. Claims 1, 2, 8, 20-29, drawn to antibody or fragment thereof and composition, comprising said antibody or fragment thereof conjugated to active substance, classified in Class 530, subclass 389.1, Class 424, subclass 178.1.

III. Claim 32, drawn to method for manufacturing a medication, comprising antibody, fragment thereof classified in Class 435, subclass 69.6.

IV. Claim 32, drawn to method for manufacturing a medication, comprising antibody or fragment thereof conjugated to active substance, classified in Class 435, subclass 69.7.

3. Groups I and II are different products. Antibody and antibody-conjugated to active substance molecules differ , with respect to their structures and physicochemical properties, which require non-coextensive searches, a person of ordinary skill in the art would not envision one in view of the other: therefore each product is patentably distinct.

4. Groups (III - I) and (IV-II) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the products can be made by various biochemical or recombinant techniques.

5. Groups III IV and are different methods. A method for manufacturing a medication, comprising antibody and method for manufacturing a medication, comprising antibody conjugated to active substance differ with respect to ingredients, method steps, and endpoints: therefore, each method is patentably distinct.

6. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

Species Election

7. This application contains claims directed to the following patentably distinct species of the claimed Invention I-IV: wherein antibody or fragment comprises:

A) F(ab),
B) F(ab),'
C) F(ab)'$_2$ or,
D) scFv.

These species are distinct because their structure physicochemical properties and mode of action are different and a person of ordinary skill in the art would not envision one in view of the other. The examination of species (A)-(D) would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

8. This application contains claims directed to the following patentably distinct species of enzyme which is chosen from the enzymes recited in claims 21 –26.

These species are distinct because their structure physicochemical properties and mode of action are different and a person of ordinary skill in the art would not envision one in view of the other. The examination of species would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 20 is generic.

9. This application contains claims directed to the following patentably distinct species of the claimed Invention I-IV: wherein antibody or fragment binding epitope of:

A) pathogenic micro-organism or.

B) pathogenic compound.

These species are distinct because their structure physicochemical properties and mode of action are different and a person of ordinary skill in the art would not envision one in view of the other. The examination of species (A)-(B) would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

10. This application contains claims directed to the following patentably distinct species of the claimed Invention I - IV, wherein micro-organism is chosen from a group recited in claim 29.

These species are distinct because their structure physicochemical properties and mode of action are different and a person of ordinary skill in the art would not envision one in view of the other. The examination of species would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

It is also noted that amended claim 27 should read "...of claim 2" rather than "...foregoing claims 2 through 26".

11. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

12. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskyi, Ph.D.
Patent Examiner
Technology Center 1600
March 20, 2002

PHILLIP GAMBEL, PH.D.
PRIMARY EXAMINER
TECH CENTER 1600
3/21/02